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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,670	03/12/2001	Wei Shao	CL000524	8111

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CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
WEGERT, SANDRA L	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,670	SHAO ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communicati n appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Information Disclosure Statement, submitted 1 April 2002, has been entered into the record as Paper 6. Reference No. 2 on the Information Disclosure Statement PTO 1449 was lined through by the Examiner because: the reference was incomplete in that no author, date or reference number was given. In addition, the reference may contain privileged information that should not be publicly disclosed. The Amendment filed 27 March 2003 (Paper No. 12) has been entered. Claims 1-3, 5-7 and 10-23 are canceled. Claim 24 was amended. Claims 4, 8, 9, and 24-29 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections/Rejections

Withdrawn Objections and/or Rejections

Title

The objection to the title as set forth at p. 2 of the previous Office Action (Paper No. 10, 27 November 2002) is *withdrawn* in view of the amendment which introduced a new title (Paper No. 12, 27 March 2003).

URL's

The objection to the specification because it contained browser-executable code as set forth at p. 3 of the previous Office Action (Paper No. 10, 27 November 2002) is *withdrawn* in view of the amendment which removed all hypertext links from the disclosure (Paper No. 12, 27 March 2003).

35 USC § 112, second paragraph-indefiniteness.

The rejection of Claim 24 because the specification does not teach how to recombinantly produce a polypeptide from the complementary nucleic acid, as set forth at p. 9 of the previous Office Action (Paper No. 10, 27 November 2002), is *withdrawn* because Claim 24 was amended to refer to a polynucleotide that encodes a polypeptide (Paper No. 12, 27 March 2003).

Maintained Objections and/or Rejections

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 4, 8, 9, and 24-29 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 3-9 of the previous Office Action (Paper No. 10, 27 November 2002). Claims 4, 8, 9, and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the

previous Office Action (Paper No. 10, 27 November 2002), one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to a nucleotide that encodes a protein that possessing approximately 72-84% homology to known transporter enzymes, such as *Solute Carrier 26* (2003, Markovich, D., Accession No. SLC26A1) and Sulfate Anion Transporter 1 (2002, Lohi, et al, Accession No. Q9H2B4). As discussed in the previous Office Action (p. 4), no well-established utility exists for newly-isolated complex biological molecules. The specification does not disclose experiments that impart any specific function for the polypeptide encoded by the claimed nucleotide in the context of the cell or organism. The specification does not teach the skilled artisan how to use the transporter peptide for any unique or specific purpose. For example, there is no disclosure of the use of substrates for the transporter, or changes in transporter processes in transfected cells, or the phenotypes of "knock-in" or "knock-out" organisms, or of flux assays, or of diseases caused by an overactivity or underactivity of the transporter. The skilled artisan is not provided with sufficient guidance to use the claimed polynucleotide for any unique purpose.

Applicants argue (page 8; Paper No. 12, 27 March 2003) that the nucleotides of the instant Specification encode molecules that have "uses within the commercial marketplace in the drug development cycle, since they encode previously unidentified members of important pharmaceutical targets."

Applicant's arguments have been fully considered but they are not persuasive for the following reasons:

The polypeptide of the Instant Specification and the polynucleotides encoding it are currently unidentified molecules. Very little information is given in the Specification about specific substrates of the polypeptide encoded by the claimed polynucleotide(s), nor of disease states due to mutant polynucleotides. The transporter cannot be an "important pharmaceutical target" until a specific role within an organism is disclosed as well as distinguishing details about its specific function. For example, Vasudevan, et al (2001, PNAS, 98: 6092-6097) found that the *LdNT1* transporter in Leishmania flukes was responsible for the drug resistance that was sometimes encountered when anti-parasitic drugs have been given to patients. This is an example of a specific function attributable to the *LdNT1* transporter of Leishmania flukes.

In addition, Applicants contend (page 8, Paper 12, 11 April 2003) that the courts have defined Utility requirements more broadly than those applied in examination of the current Application. They cite *Brenner v. Manson* (148 USPQ 689), *Nelson v. Bowler*, (206 USPQ 881) and *Juicy Whip v. Orange Bang* (51 USPQ-2d, 1700). Applicant's arguments have been fully considered but they are not persuasive for the following reasons:

The fact patterns of the cases cited by the Applicant are significantly different than those used to examine the instant Application (see the current Utility Guidelines, Federal Register, 2001, 66: 1092-1099). The cited court decisions are therefore not significant or binding with regard to the instant rejections. Furthermore, the Utility Guidelines themselves discuss *Brenner v. Manson* (148 USPQ 689), stating that the case was not persuasive in terms of establishing a utility for a polynucleotide based on homology (Federal Register, 2001, 66: page 1094, Comment 9).

Applicants further argue (pages 9 and 10, Paper No. 12, 27 March 2003) that the nucleotide of the instant Specification encodes a sulfate transporter, and that homology of the disclosed polypeptide with a class of proteins already having utility shall impart sufficient utility on the novel polypeptide and on the polynucleotide encoding it. However, the polypeptide of the Instant Specification and the polynucleotide encoding are, as yet, unidentified molecules. Although, they possess fairly high (72-84%) homology to known transporters, very little additional information is given in the Specification about a unique or specific function for the claimed polynucleotide. For example, Pendred syndrome, referred to by the Applicant on pages 9 and 10 of Paper No. 12 (27 March 2003) and in the Specification (p. 13), can be traced to a single specific iodide/chloride co-transporter (Everett, et al, 1999, PNAS, 96: 9727-97320). This association of a disease with a defect in a particular transporter is a good example of a disclosure that does impart a function to a particular gene or polypeptide.

Applicants argue against the Utility/Enablement rejection by discussing the usefulness of transporter proteins as pharmacological targets (see for example: page 8, third paragraph; page 10, fourth paragraph; page 11, third paragraph- Paper No. 12, 27 March 2003). Indeed, specific pharmacological data is precisely the type of evidence that would serve to enable the instant invention. Despite the Applicant's arguments (p. 8, Paper No. 12, 27 March 2003) the Patent Office makes clear that the usefulness of new polynucleotides does not include "entry point" and speculative experiments (Federal Register, 2001, 66: 1094). There is no evidence that the protein disclosed in the instant Specification functions as an anion transporter, a sulfate transporter, a multi-drug resistance translocase or even as a transporter protein. However, even if it were established as such, additional specific functional assays would be needed since this

family of proteins is very large and enormously varied (Jones, et al, 2000, Eur. J. Biochem., 267: 5298-5305). Transporters bind to and translocate a wide-variety of small molecules in organisms. Even closely-related family members sometimes work very differently and have different specific functions in the organism. For example, Bisson, *et al,* studied yeast transporter knock-out phenotypes, and found little correlation between homology and the substrate transported (Bisson, et al, 1993, Crit. Reviews Biochem. Mol. Biol. 28: 259). They found that *Gal2* and *Hxt4* displayed 83.7% homology, but *Gal2* appears to transport Galactose, while *Hxt4* appears to transport Glucose (based on knockout phenotype- compare Table 1 and Table 2A). The function of mutant transporters is often changed in unexpected way. For example, they are sometimes incapable of binding to or translocating substrates. Because of unexpected results often reported in the literature when trying to determine the function of a new transporter, one skilled in the art would not know the utility and function of the polypeptide disclosed in the instant disclosure, even if it *were* obviously a transporter because, as discussed in the related art above and the specification of the instant application: "Transporters mediate a variety of cellular functions including regulation of membrane potentials and absorption and secretion of molecules and ions across cell membranes" (p. 1 of Specification, line 22).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

SLW

6/6/03

ELIZABETH KEMMERER
PRIMARY EXAMINER